Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Evaluating the therapeutic effect of ursodeoxycholic acid on the reduction of serum bilirubin in neonates with prolonged jaundice: A randomized controlled clinical trial study

Protocol summary

Study aim

The aim of this study is to investigate the therapeutic effects of ursodeoxycholic acid on the reduction of serum bilirubin in a different target group, i.e. infants with prolonged jaundice who are hospitalized and not undergoing phototherapy.

Design

A paralleled controlled randomized clinical trial, without blinding, phase 3 on 58 patients. Four random blocks method is used for randomization.

Settings and conduct

A randomized clinical trial will be done at 17 Shahrivar Hospital, Rasht, after obtaining informed consent from parents. It is a non-blinded study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Serum bilirubin above 10 mg/dl3 Indirect hyperbilirubinemia (below 1) Exclusion criteria: Conjugated hyperbilirubinemia (direct bilirubin above 1) Disruption of TSH and T4 Clinical evidence of infection Urinary tract infection Sick neonates

Intervention groups

Intervention group: Administration of ursodeoxycholic acid capsules with a dose of 10 mg per kilogram of baby's weight daily in two divided doses to the intervention group for 5 days dissolved in cooled boiled water. Control group: No medication is prescribed to the control group and they receive the recommended expectant treatment and monitoring.

Main outcome variables

Total and direct serum bilirubin on the day of the visit and 5 days after the intervention and drug administration and checking the reduction of bilirubin and comparing the numbers in 2 groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180228038895N2**
Registration date: **2023-06-24, 1402/04/03**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-24, 1402/04/03**
Update count: **0**

Registration date

2023-06-24, 1402/04/03

Registrant information

Name

Seyedeh Azadeh Hosseini Nouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9026

Email address

dr.azadehoseini@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-31, 1402/03/10

Expected recruitment end date

2024-02-29, 1402/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the therapeutic effect of ursodeoxycholic acid

on the reduction of serum bilirubin in neonates with prolonged jaundice: A randomized controlled clinical trial study

Public title
Evaluating the therapeutic effect of ursodeoxycholic acid on the reduction of serum bilirubin in neonates with prolonged jaundice
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Serum bilirubin above 10 mg/dl Indirect hyperbilirubinemia (below 1)
Exclusion criteria:
Conjugated hyperbilirubinemia (direct bilirubin above 1) Disruption of TSH and T4 Clinical evidence of infection Urinary tract infection Sick neonates
Age
From **14 days** old to **28 days** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization process will be carried out under the supervision of the project manager and by her and with the direct supervision of the statistician and the supervisor. Children with admission criteria based on daily visits to the children's clinic are included in the study through consecutive sampling. For randomization, the quadruple random block method is used. According to the sample size of 58 and equal to 29 people in each group, 16 blocks of 4 complete blocks and one double block will be selected. The random allocation of samples is based on the sequence list that is done through the random block allocation software. Children who meet the entry criteria are randomly assigned to Group A (ursodeoxycholic acid) and Group B (control) based on the list.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University Of Medical Sciences
Street address
Siadati Ave, Namjoo Blvd
City
Rasht
Province
Guilan
Postal code
441774349
Approval date
2023-05-31, 1402/03/10
Ethics committee reference number
IR.GUMS.REC.1402.110

Health conditions studied

1

Description of health condition studied
Neonatal jaundice
ICD-10 code
P59
ICD-10 code description
Neonatal jaundice from other and unspecified causes

Primary outcomes

1

Description
Total and direct serum bilirubin
Timepoint
On the day of visit and 5 days after the intervention
Method of measurement
Measurement of serum bilirubin level in serum sample in laboratory with kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Administration of ursodeoxycholic acid capsules with a dose of 10 mg per kilogram of baby's weight daily in two divided doses to the intervention group for 5 days dissolved in cooled boiled water.
Category
Treatment - Drugs

2

Description

Control group: No medication is prescribed to the control group and they receive the recommended expectant treatment and monitoring.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
17 Shahrivar Hospital.

Full name of responsible person
Seyedeh Azadeh Hosseini Nouri

Street address
Siadati Alley, Namjoo St, Gaz Square

City
Rasht

Province
Guilan

Postal code
4167811969

Phone
+98 13 3336 9026

Email
dr.azadehoseini@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Mohammadreza Naghipour

Street address
Siadati

City
Rasht

Province
Guilan

Postal code
4167811968

Phone
+98 13 3333 5820

Email
research@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Rasht University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Seyedeh Azadeh Hosseini Nouri

Position
Proffessor

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

Street address
17shahrivar hospital, Siadati ave., Namjoo street, Gaz square

City
Rasht

Province
Guilan

Postal code
4167811969

Phone
+98 13 3336 9026

Fax

Email
Dr.azadehoseini@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Seyedeh Azadeh Hosseini Nouri

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Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Regarding ethical issues

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available